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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,852	09/30/2003	Jacqueline E. Heard	MBIO-001/84US 132976-2004	1145
12/06 7590 04/15/2011 COOLEY LLP 777 6th Street, NW, Suite 1100 Washington, DC 20001				
EXAMINER KRUSE, DAVID H				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/675,852

Applicant(s)

HEARD ET AL.

Examiner

DAVID H. KRUSE

Art Unit

1638

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2010 and 08 October 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 78-98 is/are pending in the application.
- 4a) Of the above claim(s) 78-84 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 85-98 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-945)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date No Dates
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

STATUS OF THE APPLICATION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8 November 2010 has been entered.
2. The claims amendment after final filed on 8 October 2010 have been entered.
3. The double patenting rejection over U.S. Patent Application 10/286,264 is now moot because said application has been abandoned.
4. The double patenting rejection over U.S. Patent Application 11/069,255 is withdrawn in view of the claims amendment.

Election/Restrictions

5. Newly submitted claim 78-84 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The instant claims are directed to a method invention not originally presented in the claims filed on 30 September 2003.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 78-84 are withdrawn from consideration

as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Information Disclosure Statement

6. The Information Disclosure Statements filed on 18 November 2010 have been considered. Those references crossed out are not publicly available disclosures. Those U.S. Patent Applications crossed out have been considered.

Priority

7. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicants' response has been fully considered (pages 5-7 of the Remarks). Applicants' evidence supports their claim of priority to U.S. Provisional Application 60/166,228 filed on 17 November 1999. See the document filed 15 April 2010 titled "Summary of Overexpressor G482, Family CATT". Applicants' assertion that there is sufficient written description support in U.S. Provisional Application 60/125,814 filed 23 March 1999 is not found to be persuasive (pages 6-7 of the Remarks filed on 8 October 2010). The Examiner acknowledges the typographic error in referring to SEQ ID NO: 14 in the Office action mailed on 15 October 2009, pages 2-3. The instant claims are directed to SEQ ID NO: 4, encoded by SEQ ID NO: 3. As previously discussed U.S. Provisional Application 60/125,814 filed 23 March 1999 does not adequately support the instant claims under 35 U.S.C. 112, first paragraph. U.S. Provisional Application 60/125,814 does not describe the claimed method steps as they relate directly to instant SEQ ID NO: 4 (page 6, 3rd and 4th paragraph of the Remarks). At page 7 of the Remarks, Applicants are arguing that

"does the art with the exact same sequence have adequate description, enablement and utility whereas the disclosure of the sequence in Applicants' disclosure does not?". The Examiner does not find the issue of inherency of function, and the requirement that support for the claimed invention under 35 U.S.C. 112, first paragraph must be found in any previous application to which Applicants claim benefit/priority, to be interchangeable. A prior application must provide adequate support under 35 U.S.C. 112, first paragraph for the claimed invention in a later filed application.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 85, 86, 88, 89, 91-94, 97 and 98 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 8 July 2010. Applicant's arguments filed 8 October 2010 have been fully considered but they are not persuasive.

Applicants claim method of making a transgenic seedling or more mature plant comprising a recombinant polynucleotide encoding a polypeptide that is at least 95-98% identical to SEQ ID NO: 4.

Applicants describe a transgenic plant comprising a recombinant polynucleotide encoding instant SEQ ID NO: 4 operably lined to a constitutive CaMV 35S promoter that are more tolerant to high NaCl (salt) in a germination assay than an equivalent non-transformed plant (see Table 6, page 95 of the instant Specification).

Applicants do not describe recombinant polynucleotides or plants transformed therewith, that confer tolerance to salt or osmotic stress that encodes a polypeptide that is at least 95-98% identical to SEQ ID NO: 4.

Hence, it is unclear that Applicants were in possession of the invention as broadly claimed. It was recognized in Swindell et al. (2007) "The biological limitations of transcriptomics in elucidating stress and stress responses." *Heredity* 99: 143-150, that "[c]andidate genes *with a well-supported role in stress-response pathways* provide good prospects for subsequent experimental study" (*emphasis added*; page 149, left column), but "[t]he identification of temperature-related genes [i.e., regulated in response to environmental changes] through microarray analysis represents *only a first step* towards understanding their role in cold- and heat-stress- regulatory *pathways*" (*emphasis added*; page 149, left column). Given the nature of the art of the instantly claimed invention, Applicants' burden to show possession of the invention as broadly claimed would be substantial given what those skilled in the art would view as being in Applicants' possession based on the description of the claimed invention.

Applicants argue that the disclosure in the multiple sequence alignment in Figures 6A-6F, showing the B domains of the G482 related sequences, indicated consensus residues by boldface. Applicants argue that the boldfaced residues in the

consensus sequence that appears at the bottom of Figures 6A through 6C in their respective positions are uniquely found in the non-LEC I-like clade. Applicants argue that the non-LEC I-like clade is distinguished by a B domain comprising: Asn-(Xaa)₄-Lys-(Xaa)_{33_34}-Asn-Gly; and the G482 subclade is distinguished by a B-domain comprising: Ser-(Xaa)₉-Asn-(Xaa)₄-Lys-(Xaa)_{33_34}-Asn-Gly. This argument is not found to be persuasive. The evidence in Table 6 (page 95 of the specification) shows that the G482 polypeptide (instant SEQ ID NO: 4) confers heat tolerance when overexpressed in a plant, whereas the G481 polypeptide does not but does confer drought tolerance. The G485 and G3395 polypeptides do not confer either heat tolerance or drought tolerance to a transgenic plant but tolerance to high salt. In addition, the type of tolerance conferred by the G481 polypeptide appears to be relative to the promoter used. Hence, the conservation of structure is not necessarily an indication for conservation of function in the instant case.

Applicants argue that consensus sequences, and their utility in determining function of a sequence, are well known in the art.

Applicants argue that it is art recognized that multiple sequence alignments, such as Figures 6A-6F, may be used to provide guidance to understand and identify related sequences. Applicants argue that it is art-recognized that with such an alignment, related sequences with similar functions may be identified by comparing evolutionarily conserved residues and conserved domains within polypeptide alignments. This argument is not found to be persuasive as addressed above by Swindell *et al* 2007.

Applicants argue that the specification and sequence listing provide numerous closely related sequences that function as does SEQ ID NO: 4.

Applicants argue that since the standard for the written description requirement is that the disclosure of the application "reasonably conveys to the artisan that the inventor had possession at the time", Applicants have met the written description requirement and one of skill in the art would clearly understand that the Applicants had possession of the claimed invention. These arguments are not found to be persuasive. Da Costa e Silva (U.S. Patent 6,677,504, originally cited in the Office action mailed on 11 April 2007, and addressed by Applicants in the response filed 18 September 2007, page 12, 1st and 2nd paragraphs) actually state that "the cellular processes leading to drought, cold and salt tolerance in model, drought- and/or salt-tolerant plants are complex in nature and involve multiple mechanisms of cellular adaptation and numerous metabolic pathways" (column 1, lines 49-53). Da Costa e Silva also states that "Although it is generally assumed that stress-induced proteins have a role in tolerance, direct evidence is still lacking, and the function of many stress-responsive genes are unknown" (column 2, lines 27-31). Hence, at the time of the invention of Da Costa e Silva, one of skill in the instant art would not assume the function of a transcription factor based on it's structural features, but would in fact deem empiric evidence of specific function as required.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 85-98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards *et al* (July 1998, Plant Physiology 117: 1015-1022) in view of Harada *et al* (U.S. Patent 6,235,975 B1, filed 24 June 1998) and in further view of Edwards (16 September 1997, Accession No. Y13724, Genbank Sequence, NCBI, National Library of Medicine, National Institutes of Health, Bethesda, MD). This rejection is repeated for the reason of record as set forth in the last Office action mailed 8 July 2010. Applicants' arguments filed 8 October 2010 have been fully considered but they are not persuasive.

Edwards teaches a recombinant polynucleotide encoding the AtHAP3b CAAT-box transcription factor having 874 nucleotides identical to that of Applicant's SEQ ID NO: 3, encoding 188 of 190 amino acids of Applicant's SEQ ID NO: 4. The AtHAP3b CAAT-box transcription factor taught by Edwards has the "conserved domain" of Applicants' SEQ ID NO: 4. Edwards teaches that expression of the AtHAP3b CAAT-box transcription factor in leaves from plants grown in soil but not in those from liquid culture may suggest environmental regulation of this gene, perhaps in relation to osmotic stress (page 1021, left column, 2nd paragraph). Edwards teaches that further research is required to understand the regulation of this factor and its role in developmental and environmental responses. Edwards 1997 is cited as evidence that the AtHAP3b, CCAAT box binding protein as publicly disclosed on 16 September 1997.

Edwards does not specifically teach a transgenic plant comprising said recombinant polynucleotide.

Harada teaches that at the time of Applicant's invention, it was obvious to transform plants with recombinant polynucleotides encoding CAAT-box transcription factors. Harada teaches a transgenic plant comprising a recombinant nucleotide sequence encoding a LEC1 polypeptide that comprises a CCAAT binding factor domain. Harada teaches that said recombinant nucleotide sequence can be operably linked to a constitutive promoter (claim 7), an inducible promoter (claim 9) or a tissue-specific promoter (claim 11). Harada teaches a method of transforming a plant by selecting a polynucleotide, inserting into an expression vector, introducing said vector into a plant or plant cell and selecting a transformed plant (see column 13, lines 49-58; columns 15-17; and column 20, last paragraph to column 21). Harada teaches that the transgenic plant can be a dicot, a monocot or a gymnosperm (column 21, lines 31-45).

The claims would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention, because it would have been obvious to isolate a polynucleotide encoding the complete AtHAP3b gene and transform a plant with the AtHAP3b CAAT-box transcription factor taught by Edwards. The invention as a whole is directed to a transgenic plant. The characteristic of abiotic stress tolerance would have naturally flown from the use of the AtHAP3b CAAT-box transcription factor to transform a wild-type plant. In addition, Edwards teaches that the AtHAP3b CAAT-box transcription factor appears to be expressed in relation to osmotic stress and hence, would have motivated one of ordinary skill in the art to produce a transgenic plant. Hence, it would have been obvious to produce a transgenic plant and select said plant based on a greater tolerance to osmotic stress. Given the success of Harada in making

a transgenic plant overexpressing the LEC1 CCAAT-box transcription factor, one of ordinary skill in the art would have had a reasonable expectation of success.

Applicants argue that neither of the references cited by the Office teaches producing and selecting a transgenic plant exhibiting enhanced yield or increased tolerance to salt or osmotic stress. Applicants argue that the combination of the art fails to disclose the presently claimed methods. Applicants argue that there is nothing in the cited art, alone or taken together, that would suggest producing a plant transformed with SEQ ID NO: 4 and selecting for the claimed traits. Applicants argue that a person of average skill in the art would not have been motivated to choose from all of the sequences available at the time of the art, amplify and clone the instantly claimed sequence, transform plants, and select for the claimed traits.

Applicants argue that as Edwards et al. indicates on page 1010, column 1, "[t]he open reading frame in AtHAP3a is the only one that starts with a Met, suggesting that the ESTs encoding *AtHAP3b*, *AtHAP5a*, and *AtHap5b* are truncated clones." Applicants argue that according to the Examiner's own statement, the combination of the art does not teach all of the elements of the instantly claimed invention: "oligonucleotides and a partial sequence [Y13724] are not SEQ ID NO: 14 (sic) or nucleic acid encoding it" (page 9 of the Remarks).

The arguments as directed to "enhanced yield" are not addressed as that subject matter is deemed non-elected by original presentation. In addition, Applicants' arguments concerning page 1010, column 1 of Edwards *et al* is unclear as the reference begins on page 1015.

Applicants' remaining arguments are not found to be persuasive. Edwards had taught that the AtHAP3b was a partial open reading frame (which begins with arginine-Arg), consequently putting those of ordinary skill in the instant art at the time of Applicants' invention that a completed open reading frame need to be isolated. Edwards had taught that expression of the AtHAP3b appears related to osmotic stress. Edwards teaches that additional steps standard in the art was required to understand the regulation of this factor and its role in developmental and environmental response. Harada had taught what one of ordinary skill in the instant art at the time of Applicants' invention would have considered to be standard or routine experimentation. What Applicants' had reduced to practice would have been *prima facie* obvious to those of ordinary skill in the art at the time of Applicants' invention. Edwards teaches that expression of the AtHAP3b CAAT-box transcription factor in leaves from plants grown in soil but not in those from liquid culture may suggest environmental regulation of this gene, perhaps in relation to osmotic stress (page 1021, left column, 2nd paragraph). Screening for drought or salt tolerance would have been obvious osmotic stresses recognized in the plant arts at the time of Applicants' invention.

Conclusion

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The central FAX number for official correspondence is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-1600.

/David H Kruse/
Primary Examiner, Art Unit 1638
11 April 2011